**NDA 21-782 ROZEREM (ramelteon)**

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**PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

## I. GOAL(S):

The goal of this REMS is to communicate potential risks coincident with use of ROZEREM to the patient in a manner that is understandable to the layman.

## II. REMS ELEMENTS:

### A. Medication Guide

Each ROZEREM prescription will be dispensed with a Medication Guide.

The Medication Guide will be included at the end of the prescribing information as a perforated attachment. Additional Medication Guides will be provided to the dispensing pharmacies to ensure that each patient gets a Medication Guide at the time the prescription is filled.

Each packaging configuration including bottles, cartons and samples will contain a Medication Guide. The labels and cartons state that the drug must be dispensed with a Medication Guide.

On the Takeda Pharmaceuticals North America and ROZEREM websites, the Medication Guide will be available.

Therefore, Takeda have met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

### B. Communication Plan

This REMS for ROZEREM does not include a Communication Plan other than the Medication Guide described above.

### C. Elements To Assure Safe Use

This REMS for ROZEREM does not include other elements to assure safe use other than the Medication Guide described above.

### D. Implementation System

Because this REMS for ROZEREM does not include other elements to assure safe use, an implementation system is not required.

### E. Timetable for Submission of Assessments

1st FDAAA Assessment: 18 months from approval
2nd FDAAA Assessment: 3 years from approval
3rd FDAAA Assessment: 7 years from approval

Takeda will submit the assessments within 60 days of the close of the intervals as noted above.